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Patent
030639-0027-UTL1
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In re the Application of:

Orville G. Kolterman, et al.

Serial No.: 09/889,330

International Application Filing Date: January
14, 2000

For: **NOVEL EXENDIN
FORMULATIONS AND METHODS OF
ADMINISTRATION THEREOF**

Group Art Unit: 1614

Examiner: To be assigned

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In compliance with Applicants' duty under 37 CFR 1.56, the following information is brought to the attention of the Examiner. The items are listed on the attached form PTO/SB/08A and copies are enclosed for the convenience of the Examiner. Applicants respectfully request that an initialed copy of the PTO/SB/08A be returned with the next Communication.

It is believed that no fee is due for this submission since it is being filed before the mailing of a first Office Action on the merits. If, however, any fee should become due or credit become payable during the pendency of this application, the Patent Office is authorized to charge or credit the same to Deposit Account 50-1273.

CERTIFICATE OF MAILING
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August 20, 2002
Date of Deposit

Laura Largey
Laura Largey

Respectfully submitted,
Kolterman et al.

Dated: August 19, 2007

By: Lisa M. McGeehan
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	09/889,330
				Filing Date	January 14, 2000
				First Named Inventor	Young
				Art Unit	1614
				Examiner Name	TBA
Sheet	1	of	4	Attorney Docket Number	030639.0027.UTL1

U.S. PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	U.S. Patent Document		Publication Date MMDYYYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	AA	5,424,286		06-13-1995	Eng	

FOREIGN PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ -Kind Code ⁵ (if known)				
	AB	WO 97/46584	12-11-1997	Boehringer Mannheim GmgH	Cited in International Search Report (copy attached)	
	AC	WO 98/08871	03-05-1998	Novo Nordisk A/S		
	AD	WO 98/30231	07-16-1998	Amylin Pharmaceuticals, Inc.		
	AE	WO 99/07404	02-18-1999	Amylin Pharmaceuticals, Inc.		
	AF	WO 99/25727	05-27-1999	Amylin Pharmaceuticals, Inc.		
	AG	WO 99/25728	05-27-1999	Amylin Pharmaceuticals, Inc.		
	AH	WO 99/40788	08-19-1999	Amylin Pharmaceuticals, Inc.		
	AI	WO 99/43708	09-02-1999	Novo Nordisk A/S		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Examiner Name	TBA
Attorney Docket Number	030639.0027.UTL1

Sheet	3	of	4
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		GLP-1 Analogs," <u>Diabetes</u> , 45(Suppl. 2):152A (1996) [abstract 553]	
	AU	O'HALLORAN et al., "Glucagon-like Peptide-1 (7-36)-NH ₂ : a Physiological Inhibitor of Gastric Acid Secretion in Man," <u>J. Endocrinol.</u> , 126(1):169-73 (1990)	
	AV	ØRSKOV et al., "Biological Effects and Metabolic Rates of Glucagonlike Peptide-1 7-36 Amide and Glucagonlike Peptide-1 7-37 in Healthy Subjects Are Indistinguishable," <u>Diabetes</u> , 42:658-61 (1993)	
	AW	RAUFMAN et al., "Exendin-3, a Novel Peptide from <i>Heloderma horridum</i> Venom, Interacts with Vasoactive Intestinal Peptide Receptors and a Newly Described Receptor on Dispersed Acini from Guinea Pig Pancreas," <u>J. Biol. Chem.</u> , 266(5):2897-902 (1991)	
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	AY	SCHEPP et al., "Exendin-4 and Exendin-(9-39)NH ₂ : Agonist and Antagonist, Respectively, at the Rat Parietal Cell Receptor for Glucagon-like Peptide-1-(7-36)NH ₂ ," <u>Eur. J. Pharm.</u> , 269:183-91 (1994)	
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	BA	STOWER et al., "A Trial of Glucagon in the Treatment of Painful Biliary Tract Disease," <u>Brit. J. Surg.</u> , 69:591-2 (1982)	
	BB	THORENS et al., "Cloning and Functional Expression of the Human Islet GLP-1 Receptor," <u>Diabetes</u> , 42(11):1678-82 (1993)	
	BC	THORENS, "Expression Cloning of the Pancreatic β Cell Receptor for the Glucocretin Hormone Glucagon-like Peptide 1," <u>P. Natl. Acad. Sci. USA</u> , 89:8641-45 (1992)	
	BD	TURTON et al., "A Role for Glucagon-like Peptide-1 in the Central Regulation of Feeding," <u>Nature</u> , 379(6560):69-72 (1996)	
	BE	WANG et al., "Glucagon-like Peptide-1 Is a Physiological Incretin in Rat," <u>J. Clin. Invest.</u> , 95:417-21 (1995)	

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				Examiner Name	TBA
Sheet	4	of	4	Attorney Docket Number	030639.0027.UTL1

	BF ¹	WETTERGREN et al., "Truncated GLP-1 (Proglucagon 78-107-Amide) Inhibits Gastric and Pancreatic Functions in Man," <u>Digest. Dis. Sci.</u> , 38(4):665-73 (1993)	
	BG	WILLMS et al., "Gastric Emptying, Glucose Responses, and Insulin Secretion after a Liquid Test Meal: Effects of Exogenous Glucagon-Like Peptide-1 (GLP-1)-(7-36) Amide in Type 2 (Noninsulin-Dependent) Diabetic Patients," <u>J. Clin. Endocrinol. Metab.</u> , 81(1):327-32 (1996)	

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				Art Unit	1614
				Examiner Name	TBA
Sheet	2	of	4	Attorney Docket Number	030639.0027.UTL1

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AJ	BHAVSAR et al., "Inhibition of Gastric Emptying and of Food Intake Appear to be Independently Controlled in Rodents," 25 th Annual Meeting, November 11-16, 1995, San Diego, California, <u>Soc. Neurosci.</u> , 21:460 (Abstract) (188.8) (1995)	
	AK	D'ALESSIO et al., "Elimination of the Action of Glucagon-like Peptide 1 Causes an Impairment of Glucose Tolerance after Nutrient Ingestion by Healthy Baboons," <u>J. Clin. Invest.</u> , 97(1):133-38 (1996)	
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	AM	EISSELE et al., "Rat Gastric Somatostatin and Gastrin Release: Interactions of Exendin-4 and Truncated Glucagon-Like Peptide-1 (GLP-1) Amide," <u>Life Sci.</u> , 55(8):629-34 (1994)	
	AN	ENG, "Prolonged Effect of Exendin-4 on Hyperglycemia of db/db Mice," <u>Diabetes</u> , 45(Supp 2):152A (abstract 554) (1996)	
	AO	ENG et al., "Purification and Structure of Exendin-3, a New Pancreatic Secretagogue Isolated from <i>Heloderma horridum</i> Venom," <u>J. Biol. Chem.</u> , 265(33):20259-62 (1990)	
	AP	ENG et al., "Isolation and Characterization of Exendin-4, an Exendin-3 Analogue, from <i>Heloderma suspectum</i> Venom," <u>J. Biol. Chem.</u> , 267(11):7402-5 (1992)	
	AQ	GLAUSER et al., "Intravenous Glucagon in the Management of Esophageal Food Obstruction," <u>J. Am. Coll. Emer. (JACEP)</u> , 8(6):228-231 (1979)	
	AR	GOKE et al., "Exendin-4 Is a High Potency Agonist and Truncated Exendin-(9-39)-amide an Antagonist at the Glucagon-like Peptide 1-(7-36)-amide Receptor of Insulin-secreting β -Cells," <u>J. Biol. Chem.</u> , 268(26):19650-55 (1993)	
	AS	KOLLIGS et al., "Reduction of the Incretin Effect in Rats by the Glucagon-Like Peptide 1 Receptor Antagonist Exendin(9-39) Amide," <u>Diabetes</u> , 44:16-19 (1995)	
	AT	MONTROSE-RAFIZADEH et al., "Structure-function Analysis of Exendin-4 /	

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